

K964830

510(k) Summary**DEC 16 1996**

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- Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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- 1. Submitter name, address, contact** Boehringer Mannheim Corporation
2400 Bisso Lane
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(510) 674-0690 extension 8413
Fax number: (510) 687-1850
- Contact Person: Yvette Lloyd
- Date Prepared: December 12, 1996
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- 2. Device Name** Proprietary name: Elecsys CalCheck LH
- Common name: Calibration Verification Material
- Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3. Predicate device** The Boehringer Mannheim Elecsys CalCheck LH is substantially equivalent to the Tosoh Medic AIA Pack for FSH. (K924863)
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- 4. Device Description** The Boehringer Mannheim Elecsys CalCheck LH are manufactured using human serum albumin, luteinizing hormone, stabilizers and preservatives. The analyte is appropriately spiked into the calcheck matrix to the correct calcheck concentration levels. The calcheck are in process checked and quality controlled against the Enzygum[®] LH assay kit calibrators (prepared using a similar procedure), which have been value assigned by comparison to a 2nd International Standard (NIBSC) 80/552.
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510(k) Summary, Continued

5.
Intended use

The Boehringer Mannheim Elecsys CalCheck LH is used to verify the calibration assignment for the Boehringer Mannheim Elecsys LH assay

6.
**Comparison
to predicate
device.**

Performance Characteristics:

- The Elecsys® CalCheck™ LH were evaluated for value assignment and stability.